

Notice of Allowability	Application No.	Applicant(s)	
	09/717,450	NEUHOLD ET AL.	
	Examiner	Art Unit	
	Michael C. Wilson	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the pre-brief conference request filed 10-2-06.
2. ☒ The allowed claim(s) is/are 55-57,59-68,72-77 and 79-100.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|--|
| <ol style="list-style-type: none"> 1. <input type="checkbox"/> Notice of References Cited (PTO-892) 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____ 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | <ol style="list-style-type: none"> 5. <input type="checkbox"/> Notice of Informal Patent Application 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____ 7. <input type="checkbox"/> Examiner's Amendment/Comment 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance 9. <input type="checkbox"/> Other _____ |
|---|--|

REASONS FOR ALLOWANCE

Claims 58, 69-71 and 78 have been cancelled.

Claims 55-57, 59-68, 72-77 and 79-100 are allowed.

The following is an examiner's statement of reasons for allowance:

Written description

The rejection of claims 55-57, 59-64, 66-68, 72-77, 79 and 81-100 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention has been withdrawn.

The ordinary and customary meaning attributed to the phrase "chondrocyte-specific promoter" by those skilled in the art taken with the teachings in the specification remains limited to a promoter that provides expression that is greater in chondrocytes than in other tissues. (This interpretation of "chondrocyte-specific promoter" is broader than in the interpretation in the office action sent 11-7-05).

The art at the time of filing

Type II collagen

Zhou (J. Cell Science, 1995, 108:3677-84), showed that a construct containing a mouse type II collagen promoter/enhancer region drives expression specifically in chondrocytes, and that a smaller 182 bp enhancer fragment of this region is sufficient to drive expression in the chondrocytes of transgenic mice (Table 1 and Figures 2-4).

Aggrecan

Pirok (J. Biol. Chem., 1997, Vol. 272, pg 11566-11574) who taught the chick aggrecan promoter. The last line in the abstract of Pirok states the aggrecan regulatory region is important "in the tissue specific expression of the chick aggrecan gene." Pirok compared expression of the chick aggrecan promoter in chicken chondrocytes and fibroblasts in vitro.

Doege (J. Biol. Chem. 1994, Vol. 269:29232-40) showed that various rat aggrecan promoter constructs drive expression at a higher level in chondrocytes than in fibroblasts (Table 1, compares promoter activity in chondrocytes versus fibroblasts).

CD-RAP

The CD-RAP promoter was well known to drive expression at a greater level in chondrocytes in comparison to other cell types. This may be seen in, e.g., Dietz (J. Biol. Chem., 1996, Vol. 271:3311-16), which shows that CD-RAP is expressed only in cartilage (Figures 6-7). This may also be seen in Bosserhoff (Dev. Dyn., 1997, Vol. 208:516-25), which shows that CD-RAP is found only in cartilage (Figure 1). In addition, Xie (Matrix Biology, 2000, Vol. 19:501-09) used the mouse CD-RAP promoter to produce transgenic mice, and confirmed that the promoter only drives expression in the chondrocytes of cartilage and at a low level in mammary epithelial cells (Figures 2-7); the authors state that the CD-RAP promoter is more restricted than type II collagen (pg 505).

Others

Rhodes (Nuc. Acids Res. 1991, Vol. 19:1933-38) reported that the link promoter drives expression at a higher level in chondrocytes in comparison to other cell types. (Figure 4, comparing promoter activity in chondrocytes (CEC) to HeLa cells).

Conclusion

Given the ordinary and customary meaning attributed to the phrase by those skilled in the art taken with the teachings in the specification and the art at the time of filing, "chondrocyte-specific promoters" were limited to promoter that provided expression that is greater in chondrocytes than in other tissues and were known in the art.

Enablement

The rejection of claims 54-57, 59-64, 66-68, 72-77, 79 and 81-100 under 35 U.S.C. 112, first paragraph, enablement, has been withdrawn.

The ordinary and customary meaning attributed to the phrase by those skilled in the art taken with the teachings in the specification remains limited to a promoter that provides expression that is greater in chondrocytes than in other tissues. (This interpretation of "chondrocyte-specific promoter" is broader than in the interpretation in the office action sent 11-7-05).

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Amount of experimentation

One of skill could determine whether a promoter provided greater expression in chondrocytes than in other tissues in a transgenic mouse or rat.

Conclusion

Given the ordinary and customary meaning attributed to the phrase by those skilled in the art taken with the teachings in the specification and the art at the time of filing, "chondrocyte-specific promoters" were limited to promoter that provided expression that is greater in chondrocytes than in other tissues and were known in the art.

The claims remain free of the prior art of record.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Art Unit: 1632

Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached at the office on Monday, Tuesday, Thursday and Friday from 9:30 am to 6:00 pm at 571-272-0738.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on 571-272-0735.

The official fax number for this Group is (571) 273-8300.

Michael C. Wilson

A handwritten signature in black ink, consisting of a series of loops and a long horizontal stroke at the end.

MICHAEL WILSON
PRIMARY EXAMINER